DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Agenda
ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
October 7-8, 2004

Patricia E. Brooks
Co-Chairperson
October 7, 2004

9:00 AM **ICD-9-CM Volume 3, Procedure presentations and public comments**

Topics:

1. Insertion of Multiple Stents Pages 7-11	Ann B. Fagan Michael Cowley, MD Medical College of Virginia Richmond,VA
2. Revision of Hip Replacement Pages 11-24	Patricia E. Brooks Kevin J. Bozic, MD, MBA UCSF
3. Revision of Knee Replacement	Patricia E. Brooks Kevin J. Bozic, MD, MBA UCSF
4. Cardiac Support Device Pages 25-27	Ann B. Fagan Spencer Kubo, MD Acorn Cardiovascular, Inc.

5. Insertion of Rechargeable Neurostimulator Pulse Generator
   Pages 28 – 30
   Amy L. Gruber
   Eric Grigsby, MD
   SpectrumCare Pain Treatment Center
   Napa, CA

6. Revision or Relocation of Defibrillator Pocket Pages 31 – 32
   Patricia E. Brooks
   Joe Kelly, MD

7. Infusion of Liquid Radioisotope
   Pages 33 – 35
   Joe Kelly, MD
   Robert A. Lustig, MD
   Hospital for the University of Pennsylvania

8. Addenda Pages 36 - 38
   Amy L. Gruber

9. ICD-10 Procedure Classification System (PCS) Update
   Thelma Grant, 3M
   Rich Averill, 3M

ICD-9-CM Volume 3, Procedures Coding Issues:
Mailing Address:

Centers for Medicare & Medicaid Services
CMM, HAPG, Division of Acute Care
Mail Stop C4-08-06
7500 Security Boulevard
Baltimore, MD 21244-1850

FAX: (410) 786-0681

Pat Brooks	New e-mail: patricia.brooks1@cms.hhs.gov 410-786-5318
Ann Fagan	New e-mail: ann.fagan@cms.hhs.gov 410-786-5662
Amy Gruber	New e-mail: amy.gruber@cms.hhs.gov 410-786-1542

Summary of Meeting:
A complete report of the procedure part of the meeting, including handouts, will be available on CMS's homepage within one month of the meeting. The summary can be accessed at:
http://www.cms.hhs.gov/paymentsystems/icd9

A summary of the diagnosis part of the meeting held on October 8 can be found at:
http://www.cdc.gov/nchs/icd9.htm

ICD-9-CM TIMELINE

A timeline of important dates in the ICD-9-CM process is described below:

August 11, 2004	Hospital Inpatient Prospective Payment System final rule published in the Federal Register as mandated by Public Law 99-509. The rule can be accessed at: http://www.cms.hhs.gov/providers/hipps/frnotices.asp
October 1, 2004	New ICD-9-CM codes are implemented.
October 7-8, 2004	ICD-9-CM Coordination and Maintenance Committee Meeting
October 2004	Summary report of the Procedure part of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage at - http://www.cms.hhs.gov/paymentsystems/icd9 Summary report of the Diagnosis part of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting report posted on NCHS homepage at - http://www.cdc.gov/nchs/icd9.htm
October 15, 2004	CMS will implement a new online registration process for future ICD-9-CM Coordination and Maintenance Committee (C&M) meetings. Information on future C&M meetings will be posted on the CMS events webpage at: http://www.cms.hhs.gov/events/ A link will be established from the ICD-9-CM web page at: http://www.cms.hhs.gov/paymentsystems/icd9
Early Nov. 2004	Any new ICD-9-CM codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented on April 1, 2005 will be posted on the following websites: http://www.cms.hhs.gov/paymentsystems/icd9 http://www.cdc.gov/nchs/icd9.htm http://www.cms.hhs.gov/medlearn/icd9code.asp
January 3, 2005	On-line registration opens for the March 31 – April 1, 2005 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events/
January 12, 2005	Deadline for receipt of public comments on proposed code revisions discussed at the April 1-2, 2004 and October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2005.

January 31, 2005	Deadline for requestors: Those members of the public requesting that topics be discussed at the March 31 –April 1, 2005 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses by this date.
February 2005	Draft agenda for the Procedure part of the March 31, 2005 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9 Draft agenda for the Diagnosis part of the April 1, 2005 ICD-9-CM Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm Federal Register notice of March 31 - April 1, 2005 ICD-9-CM Coordination and Maintenance Committee Meeting will be published.
March 25, 2005	Because of increased security requirements, **those wishing to attend the March 31 - April 1, 2005** ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at http://www.cms.hhs.gov/events **Attendees must register online by March 25, 2005; failure to do so may result in lack of access to the meeting**.
March 31 – April 1 2005	ICD-9-CM Coordination and Maintenance Committee meeting. Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting **must have registered for the meeting online by March 25, 2005.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
April 1, 2005	Any new ICD-9-CM codes required to capture new technology will be implemented. Information on any new codes implemented on April 1, 2005 previously posted in early November 2004 on the following websites: http://www.cms.hhs.gov/paymentsystems/icd9 http://www.cdc.gov/nchs/icd9.htm http://www.cms.hhs.gov/medlearn/icd9code.asp
April 2005	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include the final ICD-9-CM diagnosis and procedure codes for the upcoming fiscal year. It will also include proposed revisions to the DRG system on which the public may comment. The proposed rule can be accessed at: http://www.cms.hhs.gov/providers/hipps/frnotices.asp

April 2005	Summary report of the Procedure part of the March 31, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9 Summary report of the Diagnosis part of the April 1, 2005 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
June 2005	Final addendum posted web pages as follows: Diagnosis addendum at - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at - http://www.cms.hhs.gov/paymentsystems/icd9
July 29, 2005	Those members of the public requesting that topics be discussed at the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.
August 1, 2005	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include all the final codes to be implemented on October 1, 2005. This rule can be accessed at: http://www.cms.hhs.gov/providers/hipps/frnotices.asp
August 2005	Tentative agenda for the Procedure part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage at - http://www.cms.hhs.gov/paymentsystems/icd9 Tentative agenda for the Diagnosis part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS homepage at - http://www.cdc.gov/nchs/icd9.htm Federal Register notice for the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.

September 23, 2005	Because of increased security requirements, those wishing to attend the September 29 - 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at http://www.cms.hhs.gov/events Attendees must register online by September 23, 2005; failure to do so may result in lack of access to the meeting.
September 29 – 30, 2005	ICD-9-CM Coordination and Maintenance Committee meeting. Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 23, 2005.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2005	Summary report of the Procedure part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9 Summary report of the Diagnosis part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
October 1, 2005	New and revised ICD-9-CM codes go into effect along with DRG changes. Final addendum posted web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at - http://www.cms.hhs.gov/paymentsystems/icd9

Insertion of Multiple Stents

Issue:
The current ICD-9-CM configuration of angioplasty codes and stent insertion touches on, but does not adequately identify, the number of vessels operated on or the number of stents inserted.

Background:
Angioplasty has been widely used to treat certain types of blood vessel obstruction since the mid-1980s. Following angioplasty with insertion of a stent to keep the lumen of the vessel open became a common practice in the early 1990s. Initially, bare metal stents were used. Later these stents were enhanced with drug coatings. In 2003, the FDA approved drug-eluting stents for use in the United States.

At one time, angioplasty and stents were largely focused on treating single, short obstructions. Long lesions, lesions in multiple vessels, and anatomically complex lesions such as chronic total occlusions and those at bifurcations generally were treated with coronary artery bypass grafts. However, with advances in technique and design, it has now become possible to insert stents in several different vessels during the same operative episode rather than in stages. It has also become feasible to treat longer lesions within the same vessel, as well as anatomically complex lesions, by inserting multiple adjoining or overlapping stents. However, it is not now possible to identify and track these more complex procedures because of the lack of specificity in the coding system.

In addition to use in coronary vessels, angioplasty and stent insertion are also widely used in peripheral vessels, such as the femoral and renal arteries. The insertion of multiple stents is also coming into use in these sites. Angioplasty and stent insertion in precerebral vessels and intracranial vessels are more recent advances. Codes to describe the percutaneous transluminal angioplasty (PTA) and insertion of stents in these locations were created for use beginning October 1, 2004. It is anticipated that multiple stents could be used in these sites as well as the others mentioned above.

Coding Recommendation:
There are several manufacturers currently producing stents targeted for multiple vessels, and for different locations within the vascular system. In order to identify the stent numbers and location(s) that would best meet the industry's needs, CMS asked the manufacturers to work collaboratively to most logically pull this presentation together. CMS thanks (alphabetically) Boston Scientific, Cordis/J&J Corporation, Guidant Corporation, and Medtronic Vascular for their efforts on behalf of this recommendation.

There is only one recommendation being presented today, as opposed to the usual variety of choices that are given when we present coding recommendations. We will skip our usual first option, that of making no change to the coding system, as the addition of the ability to count the vessels treated and the number of stents inserted is a needed change to the current classification in order to describe the treatment that the patients receive. What we are attempting to do here today is determine the most efficient, easily understood change to coding these procedures and devices. Therefore the following proposal includes the deletion of some existing codes,

rewording of a code title, and creation of a new set of codes to generically identify number of blood vessels treated and the number of stents inserted.

Option 1:

36 Operations on vessels of heart
Includes:
Sternotomy (median) (transverse) } as operative approach
Thoracotomy }

Code also any injection or infusion of platelet inhibitor (99.20)
Add note Code also any injection or infusion of thrombolytic agent (99.10)
Code also cardiopulmonary bypass, if performed [extracorporeal circulation] [heart-lung machine] (39.61)

36.0 Removal of coronary artery obstruction and insertion of stent(s)

Revise title 36.01 ~~Single vessel p~~Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy ~~without mention of thrombolytic agent~~

Balloon angioplasty of coronary artery
Coronary atherectomy
Percutaneous coronary angioplasty NOS

Revise note Code also: ~~any insertion of coronary stent(s)~~ ~~(36.06)~~
Add note Insertion of drug-eluting coronary artery stent(s) (36.07)
Add note Insertion of non-drug eluting coronary artery stent (36.06)
Add note Number of vascular stents inserted (00.45- 00.48)
Add note Number of vessels treated (00.41 – 00.44)
Delete note ~~*Excludes:* multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation (36.05)~~

Delete code, all inclusion terms and excludes notes at:

~~36.02 Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent~~

Delete code, all inclusion terms and excludes notes at:

~~36.05 Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent~~

New subcategory

00.4 Other Vascular System Procedures

Note: These codes are to be used in conjunction with other procedure codes to provide additional information on the number of vessels involved and/or the number of stents inserted in any vessel

Code also:

Angioplasty or atherectomy of other non-coronary vessel(s) (39.50)
Insertion of drug-eluting coronary artery stent(s) (36.07)
Insertion of drug-eluting peripheral vessel stent(s) (00.55)
Insertion of non-drug-eluting coronary artery stent(s) (36.06)
Insertion of non-drug-eluting peripheral vessel stent(s) (39.90)
Percutaneous angioplasty or atherectomy of intracranial vessel(s) (00.62)
Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s) (00.61)
Percutaneous insertion of carotid artery stent(s) (00.63)
Percutaneous insertion of intracranial vascular stent(s) (00.65)
Percutaneous insertion of other precerebral (extracranial) artery stent(s) (00.64)
Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy (36.01)

New code 00.41 Procedure on single vessel
Vessel not otherwise specified (NOS)
Excludes: (Aorto)coronary bypass (36.10 – 36.19)

New code 00.42 Procedure on two vessels
Excludes: (Aorto)coronary bypass (36.10 – 36.19)

New code 00.43 Procedure on three vessels
Excludes: (Aorto)coronary bypass (36.10 – 36.19)

New code 00.44 Procedure on four or more vessels
Excludes: (Aorto)coronary bypass (36.10 – 36.19)

New code 00.45 Insertion of one vascular stent
Number of stents not otherwise specified

New code 00.46 Insertion of two vascular stents

New code 00.47 Insertion of three vascular stents

New code 00.48 Insertion of four or more vascular stents

Option 1a:
This option includes all the codes described above, but includes the concept of bifurcated vessels, and additional coding to describe that concept.

New code	00.40 Procedure on single vessel Vessel not otherwise specified (NOS) *Excludes:* (Aorto)coronary bypass (36.10 – 36.19)
New code	00.41 Procedure on two vessels *Excludes:* (Aorto)coronary bypass (36.10 – 36.19)
New code	00.42 Procedure on three vessels *Excludes:* (Aorto)coronary bypass (36.10 – 36.19)
New code	00.43 Procedure on four or more vessels *Excludes:* (Aorto)coronary bypass (36.10 – 36.19)
New code	00.44 Procedure on bifurcated vessels *Excludes:* (Aorto)coronary bypass (36.10 – 36.19)
New code	00.45 Insertion of one vascular stent Number of stents not otherwise specified
New code	00.46 Insertion of two vascular stents
New code	00.47 Insertion of three vascular stents
New code	00.48 Insertion of four or more vascular stents
New code	00.49 Insertion of bifurcation stent(s) "T"-shaped stent(s) "V"-shaped stent(s) "Y"-shaped stent(s)

The addition of specific codes for bifurcation of the vessels and stent(s) may be premature, as these devices are not readily available. We invite public discussion on this proposal.

Recommendation:
CMS recommends the selection of Option 1 as documented above. Option 1a can be evaluated at a future meeting if the need for this coding is demonstrated.

Interim coding:
Until changes are made to the coding structure, continue to use existing codes.

Revision Total Hip and Knee Replacement

Issue:
ICD-9-CM does not differentiate the type of revision hip or knee replacement procedure performed. Currently, code 81.53 is used to capture all "partial" and "total" revision hip replacement procedures, and code 81.55 captures all revision knee replacement procedures. These two codes currently capture a wide variety of procedures that differ in their clinical indications, resource intensity, and clinical outcomes.

Background:
Total joint replacement (TJR) is one of the most commonly performed and successful operations in orthopaedic surgery. In 2002, over 300,000 hip replacement and 350,000 knee replacement procedures were performed in the United States.[1] From 1998-2002, lower extremity arthroplasty procedures (DRGs 209 and 471) ranked 3rd among all inpatient DRG's in terms of total discharges among Medicare patients, and 1st in terms of total Medicare hospital charges. As the population of the United States (U.S.) ages and advances in technology lead to expansion of the indications for TJR to include younger, more active patients, the prevalence of TJR is expected to continue to increase dramatically over the next several decades.[1]

TJR operations have been shown to be highly cost-effective procedures,[2, 3] resulting in dramatic improvements in quality of life for patients who suffer from disabling arthritic conditions involving the hip or knee. Success rates of greater than 90% in terms of implant survivorship, reduction in pain, and improvement in function have been reported at 10 to 15 year follow-up.[4, 5] However, despite the excellent results that have been reported with primary TJR, factors related to implant longevity and evolving patient demographics have led to an increase in the volume of revision TJR procedures performed in the U.S. over the past decade.

Total Hip Replacement
Total hip replacement is an operation which is intended to reduce pain and restore function in the hip joint by replacing the arthritic hip joint with a prosthetic ball and socket joint. The prosthetic hip joint consists of a metal alloy femoral component with a modular femoral head made of either metal or ceramic (the "ball") that articulates with a metal acetabular component with a modular liner made of either metal, ceramic, or high-density polyethylene (the "socket").

Hip Implants and Materials
The first modern hip replacement implants were designed and implanted in England in the early 1960's. Early designs used stainless steel for the femoral component and Teflon for the acetabular component, and were held in place using methyl methacrylate cement. Early results revealed problems related to wear of the Teflon bearing surface, leading to failure of the implants and need for reoperation. In response to this problem, ultra high molecular weight polyethylene (UHMWPE) bearing surfaces were introduced, and have been the most widely used bearing surface since that time.

Today, the femoral (or "stem") portions of most hip implants are made of titanium- or cobalt/chromium-based alloys; they come in different shapes and degrees of roughness.

Cobalt/chromium-based alloys or ceramic materials (aluminum oxide or zirconium oxide) are used in making the ball portions, which are polished smooth to allow easy rotation within the prosthetic socket. The acetabular socket can be made of metal, high-density polyethylene, or a combination of polyethylene or ceramic backed by metal. Many modern implant designs are "cementless", relying on ingrowth of host bone into the prosthesis for stability rather than methyl methacrylate cement to achieve fixation of the implants. Studies have shown that cementless implants could have significant benefits in terms of improved implant longevity, particularly in younger, more active patients in whom cemented implants have been associated with a high rate of failure due to loss of fixation of the implants.[6]

Total Knee Replacement (TKR)

In a normal knee, four ligaments help hold the bones in place so that the joint works properly. When a knee becomes arthritic, these ligaments can become scarred or damaged. During knee replacement surgery, some of these ligaments, as well as the joint surfaces, are substituted or replaced by the new artificial prostheses. Two types of fixation are used to hold the prostheses in place. Cemented designs use polymethyl methacrylate cement to hold the prostheses in place. Cementless designs rely on bone growing into the surface of the implant for fixation.(AAOS Website)

Knee Implants and Materials

For simplicity, the knee is considered a hinge joint because of its ability to bend and straighten like a hinged door. In reality, the knee is much more complex because the surfaces actually roll and glide as the knee bends. The first implant designs used the hinge concept and literally included a connecting hinge between the components. Newer implant designs, recognizing the complexity of the joint, attempt to replicate the more complex motions of the knee joint and to take advantage of the posterior cruciate ligament (PCL) and collateral ligaments for support.

Up to three bone surfaces may be replaced during a TKR: the lower ends (condyles) of the thighbone (femur), the top surface of the shinbone (tibia) and the undersurface of the kneecap (patella). Components are designed so that metal always articulates against plastic, which provides smooth movement and results in minimal wear. The metal parts of the implant are made of titanium- or cobalt/chromium-based alloys. The plastic parts are made of high-density polyethylene.

Indications for Revision Hip or Knee Replacement

In most cases, hip or knee replacement surgery leads to dramatic improvements in health related quality of life by reducing pain and improving function for patients with arthritis. The vast majority of hip and knee replacements last for up to 15 to 20 years or more, making total joint replacement surgery one of the most successful and cost-effective interventions in all of health care.[3, 7] However, after an extended period of *in vivo* use, hip and knee replacements can fail, necessitating revision surgery. Common reasons for revision joint replacement surgery include mechanical loosening of the prosthesis (also referred to as "aseptic loosening"); wear of the bearing surface, particularly common with polyethylene, causing (at times extensive) resorption of the bone around the prosthesis; infection; dislocation of the prosthetic joint; fracture of the

bone around the implant (also referred to as “peri-prosthetic fracture”); implant fracture; technical error; and pain.[4, 5]

Wear of Articular Bearing Surface

All hip and knee replacements have an articular bearing surface that is subject to wear (the acetabular bearing surface in the hip and the tibial bearing surface in the knee). Traditionally, these bearing surfaces have been made of UHMWPE, although newer materials (both metals and ceramics) have been used as bearing surfaces more recently. Earlier hip and knee implant designs had non-modular bearing surfaces, but later designs included modular articular bearing surfaces, to reduce inventory and to potentially simplify revision surgery. Wear of the articular bearing surface occurs over time, and has been found to be related to many factors, including the age and activity level of the patient.[4, 8] In some cases, wear of the articular bearing surface can produce significant wear debris particles, which can cause peri-prosthetic bone resorption (also known and osteolysis, see below) and mechanical loosening of the prosthesis. Wear of the bearing surface can also lead to instability and/or prosthetic dislocation, and is a common cause of revision hip or knee replacement surgery.

Aseptic/mechanical loosening of the implants

The most common mechanism of long-term failure of hip and knee replacement surgery is mechanical loosening of the implants, also referred to as “aseptic loosening”. Aseptic loosening can occur as a result of breakdown of the cement mantle with cemented implants, or failure of bony ingrowth with cementless implants. Aseptic loosening is also often associated with particulate wear debris from the joint replacement bearing surface, leading to peri-prosthetic bone resorption (also referred to as “osteolysis”, described below).

Osteolysis

The term osteolysis refers to peri-prosthetic bone resorption that occurs in response to particulate wear debris that is generated at the joint replacement bearing surface. Long-term retrieval studies have demonstrated that sub-micron wear particles from the bearing surface elicit a biological response that leads to destruction of host bone.[8] This progressive bone loss can lead to pain, loss of fixation and mechanical loosening of the implants, or peri-prosthetic fracture. Bearing surface wear and osteolysis have been shown to be related to patient activity level, and are more common in younger, more active patients. Osteolysis is also more common following hip replacement than knee replacement surgery, possibly due to differences in the mechanics of these two joints and the size of the wear particles produced. Osteolysis has also been strongly linked to polyethylene wear debris in particular, and this has led to the recent development of alternative bearing surfaces for use in hip and knee replacement surgery.[9]

Infection

Infection is an infrequent but devastating complication of total joint replacement surgery. Depending on the organism, superficial infections that occur during the peri-operative period can often be treated with local surgical debridement, antibiotics, and retention of the implants. However, deep infections that occur more than 3 months following surgery often require removal of the implants (frequently associated with extensive bone loss), implantation of a temporary antibiotic-impregnated cement spacer, a prolonged period of intravenous antibiotics, followed by

delayed reimplantation of the implants. Common causes of deep infection following total joint replacement include contamination of the wound at the time of surgery, contiguous spread from an infection near the joint, or hematogenous (blood-borne) spread, often from an invasive procedure such as dental work or colonoscopy. The results of revision joint replacement following infection have been disappointing when compared with the results following primary total joint replacement or revision joint replacement for other causes.[10]

Instability

Instability (e.g., subluxation or dislocation) of the prosthetic joint can occur as a result of factors related to the patient, the implants, or the surgical technique. Instability is a more common problem leading to failure and revision surgery in hip replacement than in knee replacement. Patients who are older than age 70, female, or have a diagnosis of inflammatory arthritis, osteonecrosis of the hip, or hip fracture all have a higher risk of prosthetic hip dislocation.[11] Additionally, the choice and positioning of the implants, and the surgical approach used can influence dislocation rates. Dislocation rates after primary hip replacement surgery range from 2-4%, with much higher dislocation rates reported following revision hip replacement procedures. First time dislocators can often be treated with closed reduction of the hip and bracing. However, recurrent dislocation dramatically impairs a patient's quality of life, and necessitates revision hip replacement surgery. Recurrent dislocation accounts for approximately 4-8% of revision hip replacement procedures.[4, 5]

Peri-prosthetic fracture

Fracture of the bone around the prosthesis can occur as a result of abnormal bone quality (e.g., osteoporosis or wear particle-induced osteolysis), or supra-physiologic loading (e.g., a mechanical fall or motor vehicle collision). Urgent surgical treatment is required in most cases of peri-prosthetic fracture. Surgical options can include fixation of the bone around the prosthesis (if the prosthesis is the well fixed and the bone quality is adequate), or revision total joint replacement with or without reconstruction of associated bony defects (if the prosthesis is loose).

Implant failure

A rare cause of failed total joint replacement is failure or breakage of the implants. Implant failures have been reported with both hip replacement implants (fracture of the polyethylene or ceramic bearing surface or the femoral stem) and knee replacement implants (fracture of the polyethylene tibial insert). Occasionally, a specific implant is associated with a high rate of early failure, as was recently seen with the Sulzer Medica Inter-Op™ acetabular implant. Investigation into the high rate of early *in vivo* failures with this implant revealed a problem with the manufacturing process that caused the failures, and ultimately led to a recall of the implant. This experience underscores the importance of a coding system that accurately depicts the specific type of revision joint replacement procedure performed.

Types of Revision Hip Replacement Procedures

Depending on the cause of failure of the hip replacement, the type of implants used in the previous surgery, the amount and quality of the patient's remaining bone stock, and factors related to the patient's overall health and anatomy, revision hip replacement surgery can be relatively straightforward or extremely complex. Revision hip replacement can involve

replacing any or all of the implants, including the femoral component, the acetabular component, and the bearing surface (the femoral head and acetabular liner), and at times involves major reconstruction of the bones and soft tissues around the hip. All of these procedures differ significantly in their clinical indications, outcomes, and resource intensity.

Isolated modular femoral head and acetabular liner exchange

Exchange of the modular femoral head and acetabular liner is one of the most common revision hip replacement procedures performed. The most frequent indications for modular femoral head and acetabular liner exchange are wear of the polyethylene bearing surface or recurrent dislocation of the prosthetic hip. In cases where the bearing surface wear is associated with peri-prosthetic bone loss (e.g., osteolysis) and aseptic loosening of the prosthesis, revision of the entire acetabular and/or femoral component may be required (see below). However, in cases where the femoral and acetabular components are well fixed and appropriately positioned, and any potential bone defects are easily accessible, the modular femoral head and acetabular liner can be replaced without removing the other components. This leads to significantly shorter patient recovery times than with procedures that require revision of the femoral or acetabular components.

Isolated acetabular component revision

Revision of the acetabular component involves removal and exchange of the entire acetabular component, including both the metal shell and the polyethylene, ceramic, or metal modular bearing surface. Common indications for acetabular component revision are wear of the modular bearing surface, aseptic loosening (often associated with osteolysis), malposition of the component (leading to recurrent dislocation), or infection. If the remaining bone stock is adequate, reconstruction can be accomplished with re-implantation of a standard hemispherical implant, slightly larger but similar to the implant used in the primary surgery. However, in cases with large amounts of bone destruction due to osteolysis or component migration, reconstruction can be much more complex, often necessitating the use of large amounts of allograft (cadaver) bone or other bone substitutes and specialized acetabular implants. In cases involving major reconstruction of acetabular bone loss, surgery and recovery times are significantly prolonged, and patient outcomes are less predictable.

Femoral component revision

Common indications for isolated femoral component revision include aseptic loosening (often associated with osteolysis), malpositioning of the components (leading to recurrent dislocation), infection, or peri-prosthetic fracture. Removal of the implant and the surrounding cement often requires specialized techniques, including osteotomizing (cutting) the femur bone to gain access to the implant and the cement, and using ultrasound probes and/or specialized instruments to remove the residual cement. Long-stemmed, specialized revision implants are often required, with or without allograft (cadaver) bone graft, depending on the amount of bone loss and the quality of the remaining host bone. Recovery times following femoral component revision tend to be longer than with isolated acetabular component revision, due to the need for protected weight bearing to allow the bone to heal to the prosthesis in many cases.

Combined femoral and acetabular component revision

Revision of both the acetabular and femoral components may be required when both implants fail for the reasons described above. This type of surgery is the most labor and resource intensive and is associated with the highest complication rate of all revision hip replacement procedures. These procedures frequently involve extensile surgical exposures, specialized revision hip implants, and specialized techniques for reconstruction of extensive bony defects. Recovery time for patients can be up to 6 months, with often prolonged periods of protected weight bearing to allow the reconstruction to heal and the implants to become ingrown. Patient outcomes following revision of both components are the least predictable of all revision hip replacement procedures.

Re-implantation from previous resection or cement spacer

In cases of deep infection of a prosthetic hip, removal of the implants with implantation of an antibiotic-impregnated cement spacer, followed by 6 weeks of intravenous antibiotics is often required in order to clear the infection. Revision hip replacement from an antibiotic impregnated cement spacer often involves complex bony reconstruction due to extensive bone loss that occurs as a result of the infection and removal of the often well-fixed implants. As noted above, the clinical outcomes following revision from a spacer are often poor due to many reasons, including limited functional capacity while the spacer is in place, prolonged periods of protected weight bearing (following reconstruction of extensive bony defects), and the possibility of chronic infection.

Peri-prosthetic fracture

Unlike most of the procedures described above, which are usually scheduled as elective surgery, revision hip replacement for peri-prosthetic fracture is frequently performed as an urgent procedure. These patients are often older and sicker (e.g., have multiple associated medical co-morbidities) than other hip replacement patients, and their bone quality tends to be poor. As a result, these procedures often require extensive bony reconstruction and the use of specialized implants. Furthermore, they are associated with higher complication rates, a higher risk of peri-operative mortality, and longer recovery times than other revision hip replacement procedures. In a recent study of hospital resource utilization among primary and revision hip replacement procedures, revision hip replacement procedures for peri-prosthetic fracture were associated with significantly longer operative times, longer hospital stays, higher complication rates, and higher costs than all other revision hip replacement procedures, even when controlling for other important variables, such as age, extent of bone loss, and associated medical co-morbidities.[12]

Types of Revision Knee Replacement Procedures

Isolated Modular Tibial Insert Exchange

Isolated removal and exchange of the modular tibial bearing surface involves replacing the modular polyethylene bearing surface without removing the femoral, tibial, or patellar implants. Common indications for this procedure include wear of the polyethylene bearing surface or instability (e.g., looseness) of the prosthetic knee joint. Patient recovering times are much shorter with this procedure than with removal and exchange of either the tibial, femoral, or patellar components.

Revision of the Tibial Component

Revision of the tibial component involves removal and exchange of the entire tibial component, including both the metal base plate and the modular polyethylene bearing surface. Common indications for tibial component revision are wear of the modular bearing surface, aseptic loosening (often associated with osteolysis), or infection. Depending on the amount of associated bone loss and the integrity of the ligaments around the knee, tibial component revision may require the use of specialized implants with stems that extend into the tibial canal and/or the use of metal augments or bone graft to fill bony defects.

Revision of the Femoral Component

Revision of the femoral component involves removal and exchange of the metal implant that covers the end of the thigh-bone (the distal femur). Common indications for femoral component revision are aseptic loosening with or without associated osteolysis/bone loss, or infection. Similar to tibial revision, femoral component revision that is associated with extensive bone loss often involves the use of specialized implants with stems that extend into the femoral canal and/or the use of metal augments or bone graft to fill bony defects.

Revision of the Patellar Component

Complications related to the patello-femoral joint are one of the most common indications for revision knee replacement surgery. Early patellar implant designs had a metal backing covered by high-density polyethylene; these implants were associated with a high rate of failure due to fracture of the relatively thin polyethylene bearing surface. Other common reasons for isolated patellar component revision include maltracking of the patella in the femoral groove leading to wear and breakage of the implant, fracture of the patella with or without loosening of the patellar implant, rupture of the quadriceps or patellar tendon, and infection.

Revision of All Components (Tibial, Femoral, and Patellar)

The most common type of revision knee replacement procedure is a complete total knee revision. A complete revision of all implants is more common in knee replacement than in hip replacement because the implants used in knee replacement are not compatible across vendors or types of prostheses. Therefore, even if only one of the implants is loose or broken, a complete revision of all components is often required in order to ensure that the implants are compatible. Complete total knee revision often involves extensile surgical approaches, including osteotomizing (e.g., cutting) the tibia bone in order to adequately expose the knee joint and gain access to the implants. These procedures often involve extensive bone loss, requiring reconstruction with specialized implants with long stems and metal augments or bone graft to fill bony defects. Depending on the status of the ligaments in the knee, complete total knee revision at times requires implantation of a highly constrained or “hinged” knee replacement in order to ensure stability of the knee joint.

Re-implantation from previous resection or cement spacer

In cases of deep infection of a prosthetic knee, removal of the implants with implantation of an antibiotic-impregnated cement spacer, followed by 6 weeks of intravenous antibiotics is often required in order to clear the infection. Revision knee replacement from an antibiotic impregnated cement spacer often involves complex bony reconstruction due to extensive bone

loss that occurs as a result of the infection and removal of the often well-fixed implants. As noted above, the clinical outcomes following revision from a spacer are often poor due to many reasons, including limited functional capacity while the spacer is in place, prolonged periods of protected weight bearing (following reconstruction of extensive bony defects), and the possibility of chronic infection.

Other Important Considerations in Revision Hip & Knee Replacement

Reconstruction of Major Osseous Defects

One of the most significant variables in determining the complexity of the procedure, resource intensity, recovery times, and patient outcomes following revision total joint replacement procedures is the extent of bone loss that has occurred around the prosthesis. In cases with minimal associated bone loss, most of the procedures described above can be accomplished with standard implants, and resource utilization, recovery times, and patient outcomes are more similar to those associated with primary hip and knee replacement. However, in cases with extensive bone loss, reconstruction of the bony defects often requires specialized implants, the use of allograft (cadaver) bone, prolonged hospitalization and recovery times, and inferior patient outcomes. In a recent study of hospital resource utilization among primary and revision hip replacement procedures, reconstruction of major bone loss was the most significant predictor of higher costs among revision hip replacement procedures.[12]

Hospital Resource Utilization in Revision Hip and Knee Replacement

There is a recently completed a study comparing detailed hospital resource utilization and clinical characteristics in over 10,000 primary and revision hip and knee replacement procedures at three high volume institutions.1[12] The purpose of this study was to evaluate differences in clinical outcomes and resource utilization among patients who underwent different types of primary and revision hip or knee replacement procedures. The study found significant differences in operative time, complication rates, hospital length of stay (LOS), discharge disposition, and hospital resource utilization among patients who underwent different types of revision hip or knee replacement procedures.

Among revision hip replacement procedures, patients who underwent both femoral and acetabular component revision had longer operative times, higher complication rates, longer LOS, significantly higher resource utilization, and were more likely to be discharged to a sub-acute care facility. Isolated femoral component revision was the next most resource-intensive procedure, followed by isolated acetabular revision, and primary hip replacement was the least resource intensive of all the procedures studied. Similarly, among revision knee replacement procedures, patients who underwent complete revision of all components had longer operative times, higher complication rates, longer LOS, and significantly higher resource utilization. Revision of one component was the next most resource-intensive procedure, and primary total knee replacement was the least resource intensive of all the procedures studied.

Additionally, the data showed that extensive bone loss around the implants and the presence of a peri-prosthetic fracture were the most significant predictors of higher resource utilization among all revision hip and knee replacement procedures, even when controlling for other significant patient and procedural characteristics.

1 Massachusetts General Hospital, Mayo Clinic, and University of California San Francisco

Need for more specific codes

The MEDPAR database provides a rich source of data for epidemiological studies related to hip and knee replacement procedures. This data has been used by many clinical investigators to investigate the epidemiology of primary and revision TJR procedures, including how clinical, demographic, surgeon, and hospital characteristics impact results in terms of complication and hospital readmission rates.[13] However, efforts to use this database to study factors related to implant longevity and specific failure mechanisms is currently limited by the ICD-9-CM coding system which does not capture the type of revision joint replacement procedure performed.

The American Joint Registry Project (AJRR) is an NIH-sponsored project that is intended to capture relevant information related to total joint replacement procedures that are performed in the U.S., including factors related to the patient, the surgeon, the hospital, the implants used, and the procedure. This information could be extremely valuable in evaluating the quality, clinical outcomes, and cost-effectiveness of TJR implants and procedures. Similar databases have been in place for almost thirty years in Scandanavian countries, including Sweden, Norway, and Finland.[5] Information from these databases has been used to improve outcomes of TJR procedures in those countries. By defining epidemiologic factors related to hip and knee replacement surgery and identifying risk factors for poor outcomes which are related to the patient, the implant, and the surgical technique, the Swedish Hip Replacement Register has helped reduce complication rates and rates of revision THA procedures in Sweden.[5]

Registries such as the Swedish Hip Replacement Register and the soon to be introduced AJRR rely heavily on claims data. More specific procedure codes could dramatically improve the quality of the data available for use in the AJRR to study specific failure mechanisms related to specific implants and surgical techniques.

Revision Hip Replacement

Current codes:

80.0 Arthrotomy for removal of prosthesis
Includes: Cement spacer

80.05 Arthrotomy for removal of prosthesis, hip

81.53 Revision of hip replacement
Partial
Total

Coding Options
Option 1: Do not create additional codes to capture revision of total hip replacement procedures. Continue to code all revision of total hip replacement procedures using ICD-9 CM code 81.53.

Option 2:

Revise codes:

80.0 Arthrotomy for removal of prosthesis
Delete: ~~Includes: Cement spacer~~
Add: Code also insertion of (cement) spacer (84.56)

Revise: 81.53 Revision of hip replacement, both acetabular and femoral components
Total hip revision
Excludes: Revision of hip replacement, acetabular component only (00.71)
Revision of hip replacement, femoral component only (00.72)
Revision of hip replacement, not otherwise specified (00.73)
Code also any removal of (cement) spacer 84.57

New codes:
New: 84.56 Insertion of (cement) spacer
New: 84.57 Removal of (cement) spacer

Create a new category in 00.7 to capture detail on other types of hip revisions as follows:

New category
00.7 Other hip procedures

00.71 Revision of hip replacement, acetabular component
Partial, acetabular component only
Excludes: Revision of hip replacement, both acetabular and femoral components (81.53)
Revision of hip replacement, not otherwise specified (00.73)

00.72 Revision of hip replacement, femoral component
Partial, femoral component only
Includes: Exchange of acetabular liner
Excludes: Revision of hip replacement, both acetabular and femoral components (81.53)
Revision of hip replacement, acetabular component (00.71)

00.73 Revision of hip replacement, not otherwise specified
Revision of hip replacement, not specified as to component(s) replaced (acetabular, femoral, or both)

Option 3:
This option includes all the codes described above, but adds the following code:

00.7X Revision of hip replacement, acetabular liner and/or femoral head

Testing by hospital coders showed some difficulty in identifying this procedure. The documentation did not always support differentiating between procedures on the acetabular versus the acetabular liner. Similar problems occurred in separating procedures performed on the femoral head and the femur. The issue of adding a code for - Revision of hip replacement, acetabular liner and/or femoral head could be addressed in a later year after coders have more experience with the other new revision codes.

Recommendation: Select Option 2, create new and revised codes as described above. Evaluate the need for the code described in Option 3 in future years.

Revision Knee Replacement

Current codes:

80.0 Arthrotomy for removal of prosthesis
Delete: ~~Includes: Cement spacer~~
Add: Code also insertion of (cement) spacer (84.56)

80.06 Arthrotomy for removal of prosthesis, knee

81.55 Revision of knee replacement

Coding Options:

Option 1: Do not create additional codes to capture revision of total knee replacement procedures. Continue to code all revision of total knee replacement procedures using ICD-9 CM code 81.55

Option 2: Modify code 81.55 for use in describing total revision of knee replacement, and create a new series of codes to better describe the other types of revision knee replacements being performed (revising tibial, femoral, or patellar component).

Revise code:
81.55 Revision of knee replacement, total (all components)
Revision of total knee replacement, NOS
Includes: Replacement of femoral, tibial, and patellar components (all components)
Excludes: Revision of only one or two components (tibial, femoral or patellar component) (00.81 – 00.84)
Code also any removal of (cement) spacer 84.57

New category:

00.8 Other knee procedures
Note: Report up to two components using 00.81 – 00.83 to describe revision of knee replacements. If all three components are revised, report 81.55.

00.81 Revision of knee replacement, tibial component
Includes: Replacement of tibial baseplate and liner
Excludes: Revision of knee replacement, total (all components) (81.55)

00.82 Revision of knee replacement, femoral component
Excludes: Revision of knee replacement, total (all components) (81.55)

00.83 Revision of knee replacement, patellar component
Excludes: Revision of knee replacement, total (all components) (81.55)

Option 3:

Same as above, but add the following code:

00.8X Revision of total knee replacement, tibial insert
Excludes: That with replacement of tibial component (tibial baseplate and liner) (00.81)

Testing by hospital coders showed some difficulty in identifying this procedure. The documentation did not always support differentiating between procedures on the tibial insert versus the tibial component. The issue of adding a code for - Revision of total knee replacement, tibial insert could be addressed in a later year after coders have more experience with the other new revision codes.

Recommendation: Select Option 2, create new codes as described above. Evaluate the need for the code described in Option 3 in future years.

References

1. American Academy of Orthopaedic Surgeons Research Staff, *Primary total hip and total knee arthroplasty projections to 2030*. 1998, American Academy of Orthopaedic Surgeons: Rosemont, IL. p. 7.
2. Laupacis, A., et al., *The effect of elective total hip replacement on health-related quality of life.* J Bone Joint Surg Am, 1993. **75**(11): p. 1619-26.
3. Chang, R., J. Pellissier, and G. Hazen, *A cost-effectiveness analysis of total hip arthroplasty for osteoarthritis of the hip.* JAMA, 1996. **275**(11): p. 858-865.
4. Berry, D.J., et al., *Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components.* J Bone Joint Surg Am, 2002. **84-A**(2): p. 171-7.
5. Malchau, H., et al., *The Swedish Total Hip Replacement Register.* J Bone Joint Surg Am, 2002. **84-A Suppl 2**: p. 2-20.
6. Daellenbach, H., et al., *Economic appraisal of new technology in the absence of survival data--the case of total hip replacement.* Soc Sci Med, 1990. **31**(12): p. 1287-1293.
7. Laupacis, A., et al., *Costs of elective total hip arthroplasty during the first year.* J Arthroplasty, 1994. **9**(5): p. 481-487.
8. Schmalzried, T.P., M. Jasty, and W.H. Harris, *Periprosthetic bone loss in total hip arthroplasty. Polyethylene wear debris and the concept of the effective joint space.* J Bone Joint Surg Am, 1992. **74**(6): p. 849-63.
9. Bozic, K.J. and Jacobs, J.J., *Why the bearing surface matters: The problems caused by bearing surface wear.* Seminars In Arthroplasty, 2003. **14**(2): p. 57-68.
10. Hanssen, A.D. and J.A. Rand, *Evaluation and treatment of infection at the site of a total hip or knee arthroplasty.* Instr Course Lect, 1999. **48**: p. 111-22.
11. Berry, D.J., et al., *The cumulative long-term risk of dislocation after primary Charnley total hip arthroplasty.* J Bone Joint Surg Am, 2004. **86-A**(1): p. 9-14.
12. Bozic, K., et al., *Hospital resource utilization in primary and revision total hip arthroplasty.* ***Submitted for Publication***.
13. Katz, J., et al., *Association of hospital and surgeon volume of total hip replacement with functional status and satisfaction three years following surgery.* Arthritis and Rheumatism, 2003. **48**(2): p. 560-568.

Cardiac Support Device

Issue:
There are no ICD-9-CM codes that describe the surgical procedure in which a cardiac support device is implanted around the ventricles of the heart. A unique ICD-9-CM code to identify this complex cardiothoracic procedure is important for tracking patient outcomes.

Background:
Heart failure affects more than 5 million people in the United States, with an estimated 550,000 new cases diagnosed each year. While great progress in treatment has been made over the last 20 years, no single therapy has demonstrated long term success in preventing or reversing the progression of heart failure. Thus, there is a need for therapy that can not only improve symptoms but also potentially reverse progression of the disease.

Heart failure progression is characterized by multiple changes in cardiac structure and function. These changes are commonly referred to as cardiac remodeling. Initially, alterations can be adaptive in nature. However, maladaptive ventricular dilation eventually occurs resulting in increased ventricular wall stress and cardiac myocyte stretching. The increases in wall stress and myocardial stretch are known to be critical mechanisms in the progressive nature of heart failure.

Drug therapy (e.g. β-blockers and ACE inhibitors) has been very helpful in the management of heart failure. These drugs block the adverse consequences of stimulation of several neurohormonal pathways and reduce overall mortality. However, heart failure continues to progress despite drug therapy, possibly because drugs do not address the fundamental pathophysiologic mechanism of increased wall stress. A therapeutic intervention, which reduces wall stress, could have important benefits in interrupting the heart failure progression cycle and the remodeling process.

The device we are discussing today is the CorCap™ Cardiac Support Device (CSD). This device is a fundamentally new therapy for the treatment of heart failure that is specifically designed to reduce wall stress. The CSD is a single-use, permanent, biocompatible, textile mesh implant that is placed around the heart and adjusted to conform to the heart, supporting the heart without acutely changing hemodynamics. This innovative device is intended to reduce wall stress, reverse the remodeling process and prevent the progression of cardiac dilation associated with heart failure. As a consequence, patients may experience an improvement in symptoms and functional status. Further, patient benefits related to reductions in hospitalizations and improvements in their quality of life are expected.

Surgical Procedure:
The CSD can be implanted concomitant to mitral valve repair/replacement or as a stand-alone procedure. It is anticipated that the CSD may also be placed concomitant to CABG in the future. If the CSD is implanted as a stand-alone procedure, it may be done off pump or using cardiopulmonary bypass based on relative patient risk as assessed by the surgeon.

The CSD is currently implanted as an inpatient procedure using a sternotomy approach. After sternotomy, the pericardium is opened to expose the heart. Baseline measurements of heart size

are obtained by determining left ventricular end diastolic dimension (LVEDD) using transesophageal echocardiography (TEE). In addition, the outside circumference and base-to-apex dimension of the heart is measured using specially designed tools provided by the manufacturer. From these measurements, one of six sizes of the device is selected for implant.

The CSD is then positioned around the ventricles with the hemline placed near the atrioventricular (AV) groove. Interrupted tacking sutures are place every 2-4 centimeters along the posterior and lateral aspects of the base of the heart to secure the device along the AV groove. The device is custom fitted by gathering excess fabric toward the anterior seam using a specially designed clamp. The tension of the CSD is evaluated for even distribution over its entire circumference to avoid shortening or excess tension on the tacking sutures. LVEDD via TEE is measured at this time to ensure that there is no excess reduction in LVEDD. Intra-cardiac pressures are also monitored by Swan Ganz catheters to ensure stability of hemodynamics. If necessary, the amount of gathered fabric within the clamp is adjusted. The excess fabric is then trimmed with the clamp in place.

Next, a running mattress stitch between the clamp and the myocardium makes a new anterior seam. The fitting clamp is removed and the new anterior seam is reinforced with a second running interrupted suture. The hemline of the CSD is then completed on the anterior side using interrupted tacking sutures spaced 2 to 4 centimeters apart.

The device is visually inspected to ensure that it conforms properly, with no excess loading on base sutures, no foreshortening of the heart, and no impedance to coronary blood flow. After visual inspection is completed, the CSD and surrounding tissue is thoroughly irrigated, and the chest is closed.

The procedure typically takes 2 hours (skin-to-skin time) when performed as the sole implant. It adds approximately 30 minutes to a concomitant mitral valve repair or replacement procedure. Patient care following the CSD implant requires intensive post-operative management. Length of stay will vary depending on the patient's clinical status, but in general, is consistent with patients undergoing mitral valve surgery. Typically, patients are followed in the ICU for approximately 2-4 days, with a total length of stay averaging 7-9 days. The CSD is a permanent implant not intended for explantation.

Cardiac Support Device: Pre-Clinical and Clinical Experience

In three different models of heart failure, animal studies have consistently demonstrated the same efficacy signal and reversal of the remodeling process. This is evidenced by significant reduction in left ventricular (LV) size (LV dimension and LV volume) and increased LV function (LV ejection fraction). Further, cardiac shape becomes more ellipsoidal and the degree of mitral insufficiency is reduced. All of these changes are consistent with a reversal of the remodeling process. Initial clinical safety studies have demonstrated similar changes in LV structure and function. These benefits were maintained for 3-4 years of follow-up.

Worldwide, there have been 310 CorCap™ CSDs implanted to date. In the United States and Canada, 142 CSDs have been implanted under an FDA investigational device exception (IDE). Enrollment in the IDE pivotal clinical trial is complete and the final pre-market approval

application module is expected to be submitted to the FDA in November 2004. FDA approval is anticipated in July 2005.

Coding Options:
Option 1:
Create a new code for this device, as it is so unique that it cannot currently be captured.

00.5 Other cardiovascular procedures

New code 00.56 Implantation of prosthetic cardiac support device around the heart
Epicardial support device
Fabric (textile) (mesh) device
Ventricular support device
Code also any:
cardiopulmonary bypass [extracorporeal circulation] [heart-lung machine] if performed (39.61)
mitral valve repair (35.02, 35.12)
mitral valve replacement (35.23, 35.24)
transesophageal echocardiography (88.72)

Excludes:
circulatory assist systems (37.61 – 37.68)
other operations on heart and pericardium (37.99)

Interim Coding:
Use code 37.99, Other operations on heart and pericardium, other, to describe this procedure.

Insertion of Rechargeable Neurostimulator Pulse Generator

Issue:
Current ICD-9-CM procedure codes do not distinguish between the type of neurostimulator pulse generator. FDA recently approved a new type of neurostimulator pulse generator battery which is rechargeable. Should new codes be created to uniquely capture rechargeable neurostimulator pulse generators versus the older type which can not be recharged?

Background:
The therapy of neurostimulation for the treatment of chronic pain consists of two key components. The first is an implantable pulse generator that is inserted in a subcutaneous pocket, usually on the abdomen or buttocks. The second is one or more leads, which are placed, either in the epidural space of the spinal column or at a targeted peripheral nerve, tunneled subcutaneously and then connected to the pulse generator.

Barring complications, leads are considered permanent. Pulse generators have a battery, which eventually wears out. When this happens, the entire generator unit must be replaced.

Pulse generators currently in use have an average life span of approximately three years. However, this varies considerably depending on the severity of each patient's symptoms and their individual needs. Generator life span can be as low as six months for patients who require high-energy output to manage their symptoms. This often means that in order to extend battery life, sub-optimal electrical settings must be chosen resulting in reduced efficacy of the therapy. Patients must undergo repeated surgeries to replace the pulse generator when it reaches end-of-battery-life.

To provide consistent relief and reduce the need for repeated surgeries, rechargeable pulse generators have recently been developed. Although they also eventually reach end-of-life, the distinct ability to recharge the battery allows for higher output over a much longer life span of up to 8 or 9 years. The new rechargeable systems expand the number of available electrodes in an implanted system. They are capable of handling 16 electrodes over 2 leads, versus current devices with 8 electrodes over 2 leads. The increased number of electrodes provides broader coverage on the spinal column, and gives the physician much greater programming flexibility. Literature indicates that this increased flexibility allows the physician to reprogram which electrodes are activated in order compensate for lead migration. This reduces the number of times the physician has to conduct a revision procedure.

The first rechargeable neurostimulator pulse generator received FDA approval in April 2004. Other rechargeable models are expected to receive FDA approval over the course of 2005. It is anticipated that rechargeable pulse generators will become the new standard in neurostimulation for those 20 –25 percent of neurostimulator patients who require high energy to treat the chronic pain.

Options:
As of October 1, 2004, ICD-9-CM codes exist for the implantation, replacement and removal of neurostimulator leads in the intracranial, spinal, and peripheral applications. No changes to the lead codes are requested.

Current pulse generator codes:
86.94 Insertion or replacement of single array neurostimulator pulse generator
86.95 Insertion or replacement of dual array neurostimulator pulse generator
86.96 Insertion or replacement of other neurostimulator pulse generator

Option 1. Continue to use the current codes available since it is anticipated that the rechargeable pulse generators will become the standard.

Option 2. Create two new codes under category 86.9, Other operations on skin and subcutaneous tissue, for insertion of rechargeable neurostimulator pulse generator and revise code title for codes 86.94 and 86.95.

New code 86.97 Insertion or replacement of single array rechargeable neurostimulator pulse generator
Rechargeable pulse generator (single array, single channel) for intracranial, spinal, and peripheral neurostimulator

Code also any associated lead implantation (02.93, 03.93, 04.92)

New code 86.98 Insertion or replacement of dual array rechargeable neurostimulator pulse generator

Rechargeable pulse generator (dual array, dual channel) for intracranial, spinal, and peripheral neurostimulator

Code also any associated lead implantation (02.93, 03.93, 04.92)

Revise code title 86.94 Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable

Add exclusion term Excludes: insertion or replacement of single array rechargeable neurostimulator pulse generator (86.97)

Revise code title 86.95 Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable

Add exclusion term Excludes: insertion or replacement of single array rechargeable neurostimulator pulse generator (86.98)

Code 86.96, Insertion or replacement of other neurostimulator pulse generator, will continue to be used for all types of unspecified neurostimulator pulse generators, when either the number of arrays or the rechargeable status is not known. Code 86.05, Incision with removal of foreign body or device from skin and subcutaneous tissue, will continue to be used for removal of pulse generator.

CMS's Recommendation:

Option 2. Listed above.

In the interim, continue to use the available pulse generator codes.

Revision or Relocation of Defibrillator Pocket

Issue:
There is no unique code for the revision or relocation of the subcutaneous pocket for the pulse generator component of defibrillator devices. These procedures are currently captured by code 37.99, Other operation on heart and pericardium. A coding specialist pointed out that when a pacemaker pocket is revised or relocated, it is assigned to a more precise code, 37.79, Revision or relocation of pacemaker pocket. The coder recommended that the analogous defibrillator procedure be removed from 37.99 and assigned to a more specific procedure code.

Background:
When a subcutaneous pocket is revised or relocated for the pulse generator component of a pacemaker device, this procedure is assigned to a very specific code, 37.79, Revision or relocation of pacemaker pocket. Revising or relocation a pocket containing the pulse generator component of an implantable cardiac defibrillator (either an automatic implantable cardiac defibrillator or a CRT-D) is a similar surgical procedure. The type of device in the pocket being revised or relocated, does not change the nature of surgery. It seems inappropriate to have a unique ICD-9-CM code to capture the revision or relocation of a pacemaker pocket and not to use the same code for revision or relocation of a defibrillator pocket. Consideration should be given to capturing all revisions and relocations of the pocket containing the pulse generator of cardiac devices within a single code, or creating a new code for those performed on a defibrillator pocket.

Options:

1. **Change the title of 37.79 as follows:**

Revise:	37.7	Insertion, revision, replacement, and removal of pacemaker leads; insertion of temporary pacemaker system; or revision of <u>cardiac device subcutaneous pocket</u>
Revise:	37.79	Revision or relocation of <u>cardiac device subcutaneous</u> pocket
Add:		<u>Revision or relocation of pacemaker, defibrillator, or other implanted cardiac device subcutaneous pocket</u>

2. **Create new code as follows:**
   New code: 00.5x Revision or relocation of implantable cardiac defibrillator subcutaneouspocket
   Revision or relocation of subcutaneous pocket for:
   Automatic implantable cardiac defibrillator (AICD)
   Biventricular AICD
   CRT-D

3. **Do not create new code. Continue to capture revision or relocation of defibrillator pocket in code 37.99, Other operation on heart and pericardium.**

Recommendation:

1. **Option 1,** revise 37.79 as described above**.**

Infusion of Liquid Radioisotope

Issue:
Should a new procedure code be created to capture infusion of liquid radioisotope? There is no specific ICD-9-CM code describing infusion of a liquid radioisotope into the brain. The current ICD-9-CM does not differentiate between the placement of different types of radioelements.

Background:
Iotrex™ is an organically bound liquid form of Iodine-125 used in intracavitary brachytherapy with the GliaSite® Radiation Therapy System (RTS). Iotrex™ is a single non-encapsulated (liquid) radioactive source. Iotrex™ I-125 liquid radioisotope was cleared for marketing in April 2001. The liquid is a solution of sodium 3-(125I) iodo-4-hydroxybenzenesulfonate and is used in a breakthrough approach to deliver brachytherapy for treatment of brain cancer. The I-125 solution is nontoxic, nonpyrogenic and water-soluble. Iotrex™ comes in a one ml glass vial. Each one ml dose provides ~195 mCi of radiation.

The delivery system for I-125 Iotrex™ is a unique cavity conforming balloon catheter. The liquid Iotrex™ is administered via injection through a self-sealing port into the primary lumen of the barium-impregnated catheter that leads to the balloon reservoir. Various sizes of balloons are available.

What it does and how it is used:
After the malignant brain tumor has been resected, a balloon catheter (GliaSite® catheter) is implanted temporarily inside the cavity. The patient is released from the hospital. After a period of 3 days to 3 weeks, the patient is readmitted. At this time, the liquid I-125 (Iotrex™) is infused into the special catheter and intracavity radiation is delivered to the target area. The emitted gamma radiation from Iotrex™ is delivered directly to the margins of the tumor bed. Because the radiation dose rapidly decreases beyond the tumor site, there is minimal damage to surrounding healthy tissue. This approach allows the physician to maximize total radiation to the target area. After 3 to 7 days, the liquid I-125 Iotrex™ is removed.

Infusion of liquid radioisotope into a special cavity-conforming balloon catheter allows the precise delivery of local radiotherapy to the tumor margins where recurrence is most likely to occur. The delivery of a high dose of radiation locally at a continuous rate may better spare normal brain tissue from adverse radiation effects.

Patient Population:
The American Cancer Society estimates that 17,000 U. S. patients will be diagnosed this year with malignant primary brain tumors. Surgical resection plus radiation is the most effective treatment available today for these patients.

Overview of Conventional Insertion of Radioactive Element:
Brachytherapy has historically involved the use of small, encapsulated radioactive sources (seeds) implanted short distances apart within a malignant tumor. Radioactive seeds are used to treat multiple tumor types (breast, prostate, and in some cases, brain). Seed brachytherapy involves the invasive placement of radioactive seeds via multiple (up to 20) steel needles into the tumor tissue. In placing these multiple radiation sources, the radiation dose is frequently non-uniform with the potential for hot and cold spots. Consequently, when traditional brachytherapy is used for brain tumors, additional surgery may be needed to remove necrotic brain tissue which results from a non-uniform delivery of radiation. This complication associated with using seed brachytherapy has limited its widespread use in treating brain cancer, despite studies showing improved survival.

Infusion of Liquid Radioisotope for Treatment of Brain Cancer:
A new intracavity-conforming balloon catheter was developed to avoid some of the problems inherent with the use of seed brachytherapy for treatment of brain cancer. The device is the GliaSite® catheter and the treatment involves the infusion of a new liquid I-125 radioisotope (trade name Iotrex™). The catheter is inserted at the time that the tumor is resected. Subsequently, the I-125 is infused, placing the radioactive source in direct contact with the resection-cavity wall and providing a dose distribution that is highly conformal with the target tissue around the cavity.

The use of this single intracavitary applicator positioned inside the tumor resection cavity during the initial surgery (in place of seed implant) provides several clinical benefits which are described below.

Significantly improved dose delivery as compared to conventional brachytherapy. Infusion of I-125 (Iotrex™) facilitates the delivery in a single application the same radiation dose that requires implantation of multiple (up to 125) radioactive seeds.

More conformal/predictable dose delivery. The conformal catheter facilitates the delivery of radiation to the target tissue in a uniform manner and therefore, preclude "hot spots" and the subsequent need to re-operate to excise necrotic tumor/tissue. In comparative testing with seed implants, liquid I-125 Iotrex™ delivered via the GliaSite® catheter provides a more conformal therapy with no target tissue under-dosing, less target tissue overdosing and no healthy tissue 'hot spots'.

Options:

Option 1. Continue to code this procedure to code 92.28, Injection or instillation of radioisotopes. To capture the removal of the catheter, code 86.09, Other incision of skin and subcutaneous tissue, should be assigned.

Option 2. Create a new code for the infusion of liquid brachytherapy radioisotope. Add exclusion terms under codes 92.27, Implantation or insertion of radioactive elements, and 92.28 to exclude this procedure.

New code	92.20	Infusion of liquid brachytherapy radioisotope I-125 radioisotope Intracavitary brachytherapy

CMS's Recommendation:

Option 1. Continue to code this procedure to code 92.28, Injection or instillation of radioisotopes. To capture the removal of the catheter, code 86.09, Other incision of skin and subcutaneous tissue, should be assigned.

In the interim, continue to code this procedure to code 92.28, Injection or instillation of radioisotopes. To capture the removal of the catheter, code 86.09, Other incision of skin and subcutaneous tissue, should be assigned.

Proposed Addenda for FY 2006

Index

Debridement

Add subterm — bursa 83.5

Add subterm — fascia 83.39

Implant, implantation

cardiac resynchronization device

Revise subterm — defibrillator (CRT-D) (total system) (device and one or more leads) 00.51

Revise subterm — pacemaker (CRT-P) (total system) (device and one or more leads) 00.50

Revise subterm — CRT-D (cardiac resynchronization defibrillator) (device and one or more leads) 00.51

Revise subterm — CRT-P (cardiac resynchronization pacemaker) (device and one or more leads) 00.50

pacemaker

cardiac (device) (initial) (permanent) (replacement) 37.80

resynchronization device (CRT-P)

Revise subterm — total system (device and one or more leads) 00.50

Insertion

cardiac resynchronization device

Revise subterm — defibrillator (CRT-D) (total system) (device and one or more leads) 00.51

Revise subterm — pacemaker (CRT-P) (total system) (device and one or more leads) 00.50

Revise subterm — CRT-D (cardiac resynchronization defibrillator) (device and one or more leads) 00.51

Revise subterm — CRT-P (cardiac resynchronization pacemaker) (device and one or more leads) 00.50

pacemaker

cardiac (device) (initial) (permanent) (replacement) 37.80

resynchronization device (CRT-P)

Revise subterm — total system (device and one or more leads) 00.50

Latzko operation

Revise code — colpocleisis ~~70.4~~ 70.8

Replacement
cardiac resynchronization device

Revise subterm defibrillator (CRT-D) (total system) (device and one or more leads) 00.51

Revise subterm pacemaker (CRT-P) (total system) (device and one or more leads) 00.50

Revise subterm CRT-D (cardiac resynchronization defibrillator) (device and one or more leads) 00.51

Revise subterm CRT-P (cardiac resynchronization pacemaker) (device and one or more leads) 00.50

Tabular List

00.50 Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT-P]

Add inclusion term That with CRT-P generator and one or more leads

Add code also note Code also electrophysiologic studies [EPS] (37.26)

00.51 Implantation of cardiac resynchronization defibrillator, total system [CRT-D]

Add inclusion term That with CRT-D generator and one or more leads

Add code also note Code also electrophysiologic studies [EPS] (37.26)

00.53 Implantation or replacement of cardiac resynchronization pacemaker pulse generator only [CRT-P]

Add code also note Code also electrophysiologic studies [EPS] (37.26)

00.54 Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only [CRT-D]

Add code also note Code also electrophysiologic studies [EPS] (37.26)

37.8 Insertion, replacement, removal, and revision of pacemaker device

Add code also note Code also electrophysiologic studies [EPS] (37.26)

37.94 Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]

Revise inclusion term Implantation of defibrillator with leads (device and one or more leads) (epicardial patches), formation of pocket (abdominal fascia) (subcutaneous), any transvenous leads, intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements ~~(electrophysiologic studies [EPS])~~

Add code also note Code also electrophysiologic studies [EPS] 37.26

37.96 Implantation of automatic cardioverter/defibrillator pulse generator only

Add code also note Code also electrophysiologic studies [EPS] 37.26

37.98 Replacement of automatic cardioverter/defibrillator pulse generator only

Add code also note Code also electrophysiologic studies [EPS] 37.26

39.50 Angioplasty or atherectomy of other non-coronary vessel(s)

Code also any:

Delete code also note ~~percutaneous insertion of carotid artery stent(s) (00.63)~~